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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/672,755	09/26/2003	Charles L. Truwit	1276.001US3	1029
21186	7590	11/14/2006	EXAMINER	
SCHWEGMAN, LUNDBERG, WOESSNER & KLUTH, P.A. P.O. BOX 2938 MINNEAPOLIS, MN 55402			TOWA, RENE T	
			ART UNIT	PAPER NUMBER
			3736	

DATE MAILED: 11/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/672,755

Applicant(s)

TRUWIT, CHARLES L.

Examiner

Rene Towa

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 09 September 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 14-27, 39 and 45-47 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 14-27, 39 and 45-47 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

1. This Office action is responsive to an amendment filed September 9, 2006. Claims 14-27, 39 and 45-47 are pending. Claims 14, 39 and 45 have been amended. Claims 1-13, 28-38 and 40-44 have been cancelled. No new claim has been added.

#### ***Specification***

2. The objection is withdrawn due to amendment.

#### ***Claim Objections***

3. The objections are withdrawn due to amendments.

#### ***Claim Rejections - 35 USC § 103***

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
5. Claims 14-18 and 25-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yoon (US Patent No. 5,797,888) in view of Nagamatsu (US Patent No. 5,762,070).

In regards to claim 14, Yoon disclose(s) a probe deflection device 20 comprising:  
an outer tube 22 having a proximal end and a distal end, the outer tube 22 including a closure 24 that is movable between an open and a closed condition, the closure having an exit hole 29 defining a travel path; and

an inner tube 26 fitted to slide within the outer tube 22 such that as the inner tube 26 slides through the exit hole, the inner tube 26 follows the travel path (see figs. 1, 3, 6 & 7).

In regards to claim 16, Yoon disclose(s) a probe deflection device wherein the closure has an actuator arm (i.e. from probe 62) accessible at the proximal end of the outer tube (see figs. 6-7).

In regards to claim 17, Yoon disclose(s) a probe deflection device wherein the closure is capable of being closed as the inner tube 26 is inserted into the outer tube 22 (see column 4/lines 42-49).

In regards to claim 18, Yoon disclose(s) a probe deflection device wherein the closure is capable of being open as the inner tube 26 is withdrawn into the outer tube 22 (see figs. 1, 3, 6 & 7; column 4/lines 42-49).

In regards to claim 25, Yoon disclose(s) a probe deflection device wherein the outer tube 22 is rotatable about the inner tube 26 (see figs. 1, 3, 6 & 7).

In regards to claim 26, Yoon disclose(s) a probe deflection device further comprising: a probe 62 inserted in the inner tube 26 (see figs. 6-7).

Yoon discloses a probe deflection device, as described above, that teaches all the limitations of the claims except Yoon does not disclose a closure having an exit hole in a closed condition of the closure.

However, Nagamatsu discloses a probe deflection 1 including a closure (11a, 11b) that is movable between a open and closed condition, the closure having an exit hole 35a in a closed condition of the closure (11a, 11b), wherein the exit hole 35a defining a travel path (see figs. 1, 3, 5, 6a-b & 8-9); wherein the exit hole 35a includes a center line that creates an oblique angle with the longitudinal axis; wherein the closure

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has an actuator arm (see fig. 2); wherein the closure is capable of being opened and closed (i.e. using actuator handles) (see figs. 1, 3, 5, 6a-b & 8-9).

It would have been obvious to one ordinary skill in the art at the time Applicant's invention was made to provide a device similar to that of Yoon with an exit hole similar to that of Nagamatsu in order to guide the device through tortuous body lumens as is well known in the art (see Nagamatsu, column 2/lines 59-67; column 4/lines 55-61; column 6/lines 38-48).

Moreover, it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide a device similar to that of Yoon with an actuator arm similar to that of Nagamatsu in order to control actuation (i.e. open and close condition) of the closure as is well-known in the art.

6. Claims 19-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yoon ('888) in view of Nagamatsu ('070) further in view of Selmon et al. (US Patent No. 6,217,527).

Yoon as modified by Nagamatsu disclose(s) a probe deflection device, as described above, that teaches all the limitations of the claim except Yoon as modified by Nagamatsu does not expressly teach that the inner tube is flexible and/or fabricated from a material having shape memory.

However, Selmon et al. discloses a device wherein the inner tube 114 is flexible (see figs. 7-9); wherein the inner tube 114 is fabricated from a material having memory (see column 12/lines 55-57).

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It would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide a system similar to that of Yoon as modified by Nagamatsu with an inner tube similar to that of Selmon et al. in order to redirect a working tool (i.e. guidewire) back into or out of the outer tube (see Selmon et al., see figures 8-9; column 11/line 60 to column 12/line 2; column 13/lines 59-61; see Nagamatsu, column 2/lines 59-67; column 4/lines 55-61; column 6/lines 38-48).

7. Claims 21-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yoon ('888) in view of Nagamatsu ('070) further in view of Werne (US Patent No. 5,782,764).

Yoon as modified by Nagamatsu disclose(s) a probe deflection device, as described above, that teaches all the limitations of the claim except Yoon as modified by Nagamatsu does not expressly teach a stylet.

However, Werne discloses a medical stylet as follows:

In regards to claim 21, Werne discloses a probe device comprising a flexible stylet capable of being inserted into the inner tube, the flexible stylet 42 having a blunt polished tip 40A (see figs. 2 & 8-10).

In regards to claim 22, Werne disclose(s) a probe device comprising a flexible stylet 42 including an imaging contrast media 46 (see figs. 2-3 & 8-10; column 9/lines 61-67; column 10/lines 18-28).

In regards to claim 23, Werne disclose(s) a probe device comprising a stylet 42 having a cavity holding the imaging contrast media 46 (see figs. 2-3 & 8-10; column 9/lines 61-67; column 10/lines 18-28).

It would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide a device similar to that of Yoon as modified by Nagamatsu with a stylet similar to that of Werne in order to locate the position of the tissue collection recess (see Werne, column 9/line 67 to column 10/line 6).

Moreover, since Werne teaches the use of a solution with a high proton density for MR image tracking (see column 10/lines 20-24), it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide a device similar to that of Yoon as modified by Nagamatsu and Werne with a saline solution marker, which is high in protons, since such a modification would amount to a design choice.

8. Claim 27 is rejected under 35 U.S.C. 103(a) as being unpatentable over Yoon ('888) in view of Nagamatsu ('070) further in view of Sidall et al. (US Patent No. 4,741,326).

Yoon as modified by Nagamatsu disclose(s) a probe deflection device, as described above, that teaches all the limitations of the claim except Yoon as modified by Nagamatsu does not teach a sheath.

However, Sidall et al. disclose(s) a probe device comprising a retractable sheath 1 (see fig. 3; column 3/lines 3-11).

It would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide a device similar to that of Yoon as modified by Nagamatsu with a sheath similar to that of Sidall et al. in order to prevent contamination of said device (see Sidall et al., column 3/lines 3-11).

9. Claim 39 is rejected under 35 U.S.C. 103(a) as being unpatentable over anyone of Selmon et al. ('527) in view of Yoon ('888) further in view of Nagamatsu ('070).

In regards to claim 39, Selmon et al. disclose(s) a method of positioning a probe in a target area that is off axis from an outer tube inserted in a biological subject, the method comprising:

inserting an inner tube 114 having a tip into the outer tube 102 having an outer surface and a closure 110 having an exit hole 122 such that the tip extends through the exit hole and beyond the outer surface of the outer tube;

inserting a probe GW into the inner tube 114 such that the probe GW extends beyond the surface of the outer tube 102; and

removing the inner tube 114 without deflecting of the probe GW (see figs. 7-9; column 13/lines 38-49 & 52-58).

Selmon et al. teach all the limitations of the claim except Selmon et al. do not teach a closure that opens and closes.

However, Yoon discloses a probe deflection method comprising a closure 24 that closes and opens (see figs. 1, 3 & 6-7; column 4/lines 42-49).

Nagamatsu discloses a probe deflection 1 including a closure (11a, 11b) that is movable between an open and closed condition, the closure having an exit hole 35a in a closed condition of the closure (11a, 11b), wherein the exit hole 35a defines a travel path (see figs. 1, 3, 5, 6a-b & 8-9); wherein the exit hole 35a includes a center line that creates an oblique angle with the longitudinal axis; wherein the closure has an actuator arm (see fig. 2).



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It would have been obvious to one ordinary skill in the art at the time Applicant's invention was made to provide a method similar to that of Yoon with an exit hole path similar to that of Nagamatsu in order to guide a working tool (i.e. perhaps a guidewire) into or out of a work area in a tortuous body lumen as is well known in the art (see Nagamatsu, see figure 4; column 2/lines 59-67; column 4/lines 55-61; column 6/lines 38-48).

Moreover, it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide a method similar to that of Selmon et al. with a closure similar to that of Yoon as modified by Nagamatsu in order to guide the device through tortuous body lumens as is well known in the art (see Nagamatsu, column 2/lines 59-67; column 4/lines 55-61; column 6/lines 38-48).

10. Claims 45-47 are rejected under 35 U.S.C. 103(a) as obvious over Selmon et al. ('527) in view of Werne ('764).

In regards to claim 45, Selmon et al. disclose(s) a method of orienting an outer tube of a probe deflection device in a biological subject, the method comprising:

inserting an outer tube 102 having a surface and an off axis exit hole 122 such that when the guidewire is fully inserted into the inner tube, the blunt tip and the inner tube distal end form a smooth blunt tip suitable for tunneling through tissue of a biological subject;

inserting a guidewire GW having an imaging marker and a blunt tip into an inner tube 114 to obturate the off axis exit hole 122;

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inserting the inner tube 114 having a distal end into the outer tube 102 such that the distal end does not extend beyond the surface of the outer tube 102;

identifying an error in orientation of the outer tube using the imaging marker; and

if the error exceeds a predetermined value, rotating the outer tube to correct the error (see figs. 7-9; column 5/lines 14-25; column 6/lines 38-48; column 10/lines 38-45; column 11/lines 6-12 & 19-25; column 12/lines 32-38; column 13/lines 38-49 & 52-58; column 15/lines 61-63).

In regards to claim 46, Selmon et al. disclose(s) a method wherein identifying an error in orientation of the outer tube comprises:

using imaging to identify the orientation of the outer tube 102 (see column 11/lines 6-12 & 19-25; column 12/lines 32-38).

In regards to claim 47, Selmon et al. disclose(s) a method wherein using imaging to identify the orientation of the outer tube comprises:

imaging the imaging marker (see column 11/lines 6-12 & 19-25; column 12/lines 32-38).

It is noted that although Selmon et al. do not expressly teach the "error" step; however, from Selmon et al.'s method, the step appears to be implicitly taught in the sense that Selmon et al. teaches every step of the method without mentioning a feedback step.

As such, it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide a method similar to that of Selmon et al. as modified by Werne with a method step involving ascertaining and correcting the

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orientation of the outer tube in order to provide feedback (i.e. controlled orientation of the outer tube) to the method since such a modification would amount to a design choice.

Selmon et al. disclose a method, as described above, that teaches all the limitations of the claims except Selmon et al. does not teach a stylet.

However, Werne discloses a method including providing a probe device comprising a flexible stylet capable of being inserted into the inner tube, the flexible stylet 140 having a blunt polished tip 140A (see figs. 6-7); wherein the flexible stylet 140 includes an imaging contrast media 46 (see figs. 2-3 & 6-10; column 9/lines 61-67; column 10/lines 18-28).

It would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide a method similar to that of Selmon et al. with a stylet similar to that of Werne in order to locate or guide the position of the device (see Werne, column 9/line 67 to column 10/line 6).

### ***Response to Arguments***

11. Applicant's arguments filed September 9, 2006 have been considered but are moot in view of the new ground(s) of rejection.

### ***Conclusion***

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rene Towa whose telephone number is (571) 272-8758. The examiner can normally be reached on M-F, 8:00-16:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

RTT



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